

HOUSE No. 1397

By Ms. Fox of Boston, petition of Gloria L. Fox and others for legislation to protect the public health and environment from select toxic biological agents. Environment, Natural Resources and Agriculture.

The Commonwealth of Massachusetts

PETITION OF:

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In the Year Two Thousand and Five.

AN ACT PROTECTING THE PUBLIC HEALTH AND ENVIRONMENT FROM SELECT TOXIC BIOLOGICAL AGENTS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

- 1 SECTION 1. The Department of Environmental Protection, in
2 cooperation with the Department of Public Health, shall adopt
3 regulations for a dangerous or exotic agents that have a high risk
4 of a life-threatening disease for which there is no available vac-
5 cine or therapy hereinafter referred to as BSL4 facilities estab-
6 lishing criteria for the selection of any superior site, guidelines for
7 their application, and procedures for the conduct of site. The pri-
8 mary consideration in adopting such regulations shall be the pro-
9 tection of public health, safety, and the environment.
10 The site selection criteria and application guidelines shall
11 ensure, at a minimum, that any superior site satisfies the following
12 site suitability requirements.

13 1. Sites shall be capable of being characterized, modeled, and
14 monitored;

15 2. Sites shall be located so that tectonic processes in the
16 vicinity, such as faulting, folding, seismic activity or volcanism,
17 will not occur which will significantly effect the ability of the site
18 to meet any performance objectives;

19 3. Sites shall be located so that surface geologic processes in
20 the vicinity, such as mass wasting, erosion, slumping, land sliding,
21 or weathering will not occur which will significantly affect the
22 ability of the site to meet any performance objectives;

23 4. Sites shall be located so that nearby activities will not
24 adversely affect the ability of the site to meet any performance
25 objectives adopted by the department of public health, or signifi-
26 cantly impair the environmental monitoring program;

27 5. Site shall be located in an area with minimal wind that
28 would exacerbate the spread of released pathogens.

29 6. The laboratory need not be physically separated from other
30 laboratories but it should not be sited next to a known fire hazards
31 (e.g., solvent storage) or be in danger of flooding.

32 7. Sites shall have sufficient land available to provide for a rea-
33 sonable buffer around the BSL4 facility, at a minimum 250 feet in
34 every direction.

35 The procedures for the conduct of site selection shall include a
36 quality assurance program designed to ensure data reliability,
37 validity, traceability, and retrievability, as well as completeness
38 and technical adequacy, for use in making any site selection deci-
39 sions or subsequent permitting determination.

1 SECTION 2. The Department of Environmental Protection, in
2 cooperation with the Department of Public Health, shall promul-
3 gate rules and regulations for the siting of BSL4 facilities. Said
4 rules and regulations shall establish site suitability standards and
5 criteria and shall include, but not be limited to, the following con-
6 siderations:

7 The location, nature and extent of any existing or potential
8 sources of public or private drinking water supplies in relation to
9 the site, including the recharge area of a sole source aquifer;

10 The relationship of the site to groundwater elevations;
11 The proximity of wetlands, as defined in section forty of
12 chapter one hundred and thirty-one;
13 The proximity of surface water bodies;
14 The proximity of flood plains;
15 The nature and extent of residential areas in proximity to the
16 site;
17 The availability and suitability of access roads to the site;
18 Whether areas adjacent to the proposed site have been previ-
19 ously used for solid waste disposal;
20 The potential for adverse impact on air quality;
21 The potential for creation of a nuisance from noise, windblown
22 litter, or the proliferation of rodents, flies or other vermin;
23 The potential for the adverse public health and safety impacts;
24 The potential impact on agricultural uses;
25 The potential adverse impact on wildlife and on wildlife
26 habitat;
27 The potential impact of increased traffic volume on roads to the
28 site;
29 The extent to which existing BSL4 facilities are located within
30 a municipality. Site assignments for new facilities are preferred in
31 municipalities without existing facilities;
32 The potential adverse impacts on communities within thirty
33 miles of the proposed site, including the potential adverse impacts
34 on the considerations stated within this section for which site suit-
35 ability standards and criteria are established.
36 The determination of the DEP and DPH on an application for a
37 BSL4 facility site assignment is not binding upon the local board
38 of health of the local municipality where the prospective site is
39 located. The local board of health must make an independent
40 review and determination of whether the proposed site complies
41 with statutory criteria.

1 SECTION 3. No BSL4 facility shall be constructed or operated
2 within the Commonwealth unless:—

3 (i) Construction and operation of the proposed facility has
4 been approved by a majority of the voters voting thereon in a
5 municipal-wide general election in the municipality in which the
6 facility would be sited; and

7 (ii) An adequate emergency preparedness plan for the proposed
8 facility has been developed, approved, and implemented by the
9 Commonwealth;

10 (iii) Effective standards applicable to the proposed facility have
11 been promulgated by the Commonwealth to protect the public
12 against health and safety hazards attributable to BSL4 materials
13 within the Commonwealth;

14 At a minimum, the following shall be submitted to the Depart-
15 ment of Public Health, Department of Environmental Protection,
16 and municipality in which the facility will be sited for review and
17 approval, prior to the commencement of construction of any BSL4
18 facility:

19 i. Small-scale layout drawing showing possible arrangement
20 of space, conceptual designs, and schematic designs.

21 ii. Topographic data, including seismic data or other pertinent
22 information.

23 iii. Existing utilities information.

24 iv. Construction schedule.

25 v. Project Plan including: Description of Project, Project
26 Implementation Strategy, Quality Assurance and Quality Surveil-
27 lance Plans, Environmental Control Plan, Occupancy Plan, Com-
28 munity Relations Plan, and Commissioning Plans.

29 vi. Worst case release scenarios for the toxic biological agents
30 that might be used in the BSL4 laboratory.

31 All construction contractors engaged in BSL4 projects shall
32 have recent and relevant experience in the planning and construc-
33 tion of bio-containment facilities. Records and references of such
34 experience shall be submitted to the Department of Public Health,
35 Department of Environmental Protection, and municipality in
36 which the facility will be sited for review and approval.

37 The Department of Environmental Protection, in cooperation
38 with the Department of Public Health, shall promulgate additional
39 regulations for the construction of BSL4 facilities that are at least
40 as stringent and protective of the public health, safety, and the
41 environment as applicable federal requirements and guidelines for
42 construction of such facilities. At a minimum, the regulations
43 shall assure that the facility is constructed to minimize the poten-
44 tial that a toxic biological agent might infect a person or escape

45 laboratory containment. The regulations shall also require the
46 facility to have redundant utilities and systems to prevent and
47 minimize the possibility of a release of a toxic biological agent.

1 SECTION 4. The Department of Public Health, in cooperation
2 with the Department of Environmental Protection, shall promul-
3 gate regulations for the operation and maintenance of BSL4 labo-
4 ratories, laboratory procedures, and the handling of biological
5 materials to be used in BSL4 laboratories that shall be at least as
6 stringent and protective of the public health, safety, and the envi-
7 ronment as applicable federal requirements and guidelines. At a
8 minimum, the regulations shall assure that the laboratory is oper-
9 ated, and its containment systems and procedures maintained, to
10 minimize to the maximum extent practicable the potential that a
11 toxic biological agent might infect a person in the laboratory or
12 escape laboratory containment. The regulations shall include at a
13 minimum:

14 All BSL4 experiments shall occur in a facility independent or
15 completely isolated from other research areas.

16 All personnel working on BSL4 experiments must conducted
17 them in Class III Biosafety cabinets or in a full-body, air-supplied
18 positive pressure personnel suits, or in more restrictive conditions.

19 Standard Microbiological Practices are adopted, documented,
20 and implemented.

21 Special Practices for BSL4 laboratories are adopted, docu-
22 mented, and implemented.

23 Standards for Safety Equipment (Primary Barriers). All proce-
24 dures within the facility are conducted in the Class III biological
25 safety cabinet or in Class II biological safety cabinets used in con-
26 junction with one-piece positive pressure personnel suits venti-
27 lated by a life support system.

28 Standards for the Laboratory Facility (Secondary Barriers)
29 There are two models for Biosafety Level 4 laboratories: (A) the
30 Cabinet Laboratory where all handling of the agent is performed
31 in a Class III Biological Safety Cabinet, and (B) the Suit Labora-
32 tory where personnel wear a protective suit. BSL4 laboratories
33 may be based on either model or a combination of both models in
34 the same facility. If a combination is used, each type must meet all
35 the requirements identified for that type.

36 The facility shall have specific procedures to ensure compli-
37 ance of BSL4 handling and experimentation with all applicable
38 BSL4 safety criteria.

39 The facility shall develop and maintain a manual of operations
40 and maintenance.

41 The manual shall comply with all Federal, State, and municipal
42 regulations.

43 The manual shall be publicly accessible with reasonable safety
44 limitations.

45 The facility shall provide adequate training for all site workers
46 in the proper handling of BSL4 materials to ensure contamination
47 controls. Such training shall include, but not be limited to:

48 Basic BSL4 Principles;

49 Basic BSL4 Protection;

50 BSL4 Biology;

51 Decontamination Methods;

52 Personnel Safety Precautions/Work Habits;

53 Accident Response Actions/Notifications;

54 Recombinant DNA use.

55 All persons and facilities with a BSL4 component proposing to
56 use rDNA must obtain a permit from the Department of Public
57 Health (“DPH”) and from the municipality where it is located if
58 required by the municipality.

59 The permit holder shall report, within thirty (30) days, to the
60 DPH any significant problems with or violations of the guidelines
61 and any significant rDNA-related accidents or illnesses.

62 Effective rodent and insect control programs must be in place
63 in facilities where rDNA use and research takes place.

64 A municipality may adopt similar and more stringent rDNA
65 requirements and restrictions.

66 Any accidental or intentional release of a toxic biological agent
67 shall be reported to the local police, fire, and health department
68 and the Department of Public Health and Department of Environ-
69 mental Protection immediately, and in no case more than twenty-
70 four (24) hours after the release.

1 SECTION 5. Every BSL4 facility shall have a security plan
2 which shall take into account the basic security threats to the
3 facility

4 The basic security threats shall include but not be limited to:—

5 1. threats equivalent to:—

6 (a) the events of September 11, 2001

7 (b) a psysical, cyber, biochemical, or other terrorist threat;

8 (c) an attack on a facility by multiple coordinated teams of a
9 large number of individuals;

10 (d) assistance in an attack from several persons employed at
11 the facility;

12 suicide attack;

13 (e) a water-based or air-based threat;

14 (f) the use of explosive devices of considerable size and other
15 modern weaponry;

16 (g) an attack by persons with a sophisticated knowledge of the
17 operations of a sensitive BSL4 facility;

18 (h) internal terrorism and sabotage; and

19 (i) fire, especially a fire of long duration; and

20 Any other threat that the DEP, DPH, or local and state police
21 determine should be included as an element of the design basic
22 threat

23 i. Security Plans

24 The facility, in coordination with local and state officials, shall
25 develop a security plan for BSL4 facilities to ensure the protection
26 of each facility against the design basis threat.

27 ii. Elements Of The Plan- A security plan shall prescribe

28 The deployment of security guards

29 a. numbers of the members of the guards at each facility;

30 b. tactics of the guards at each facility; and

31 c. capabilities of the guards at each facility;

32 Other protective measures, including:—

33 d. Coordination of security response with Federal, State, and
34 Local authorities;

35 e. restricted personnel access to each BSL4;

36 f. perimeter site security, internal site security, and fire protec-
37 tion barriers;

38 i. A security barrier of at least 250 feet;

39 g. background security checks for employees and prospective
40 employees; and

41 Sufficiency Of Security Plan

42 If at any time the facility determines that the implementation of
43 the requirements of the security plan for a BSL4 facility is insuffi-
44 cient to ensure the security of the sensitive facility against the
45 design basis threat, the facility shall immediately submit to the
46 Commonwealth a report that:—

47 (a) identifies the vulnerability of the facility; and

48 (b) recommends actions by Federal, State, or local agencies to
49 eliminate the vulnerability.

50 If the facility is incapable of defending itself from a security
51 threat the Commonwealth may supply protection to the facility at
52 cost to the facility or may require the facility to close immediately
53 and destroy its stock of toxic biological materials.

54 Security Guards

55 The Department of Public Health, in cooperation with the
56 Department of Public Safety, shall promulgate regulations for
57 security guards for facilities with BSL4 laboratories. At a min-
58 imum, those regulations shall include:

59 a. qualification standards;

60 b. training requirements;

61 c. examination;

62 d. criminal and security background checks;

63 e. disqualification of individuals who present security risks;

64 and

65 f. annual proficiency review.

1 SECTION 6. For purposes of this section, “permit proceeding”
2 includes the consideration of any application for a permit and of
3 any proposal or request to suspend, revoke, modify or renew a
4 permit. “Permit determination,” means the decision of the director
5 upon such application, proposal or request.

6 No person or persons shall operate a facility in which BSL4
7 grade materials are possessed, handled, or studied without a cur-
8 rently valid permit issued by the director. No person or persons
9 shall operate a facility that engages in any activity that may rea-
10 sonably be expected to result in the development of BSL4 grade
11 materials without a currently valid permit issued by the director.

12 The Department of Public Health shall adopt regulations with
13 respect to permit proceedings and determinations. Applications

14 for permits shall be submitted within times and on forms pre-
15 scribed by the director and shall contain such information as he
16 may

17 Public notice of every permit proceeding shall be given in the
18 manner provided by section three of chapter thirty A. The DPH
19 shall circulate information received concerning the matter pending
20 and hold a public hearing because such hearing is in the public
21 interest. The public hearing shall be in the municipality in which
22 the BSL4 facility is located, at least thirty days after giving notice
23 thereof. The DPH may, upon request of a permittee, revise a
24 schedule of compliance in an issued permit if the director deter-
25 mines that good and valid cause, for which the permittee is not at
26 fault, exists for such revision, and in such cases the provisions of
27 this paragraph for public notice and hearing shall not apply. If
28 DPH has proposed to suspend or revoke a permit, in whole or in
29 part, and if the permittee requests an adjudicatory hearing on the
30 proposed determination, the requested hearing shall be held as
31 part of the public hearing to be afforded under this paragraph.

32 The DPH shall adopt regulations with respect to permit pro-
33 ceedings and determinations. Applications for permits shall be
34 submitted within times and on forms prescribed by DPH and shall
35 contain such information as it may require.

36 DPH shall grant a permit only if it determines that the facility
37 will not be a threat to the public health, safety, and the environ-
38 ment and that the facility will comply with the requirements of
39 federal and state laws and regulations for BSL4 facilities.

40 Every permit shall specify limitations on use and possession of
41 BSL4 grade materials, interim and final deadlines where appro-
42 priate for compliance, the term for which the permit is issued,
43 which may not be in excess of five years, and such requirements
44 of proper operation and maintenance, monitoring, reporting, and
45 inspection as DPH may prescribe. Permits may specify additional
46 requirements that the director deems necessary to safeguard the
47 community from dangers posed from BSL4 use.

48 The renewal of permits after their expiration, which is not to
49 exceed five years, must be submitted in a timely manner.

50 A facility which continues operation with an expired permit
51 shall be penalized by DPH for every day it operates without a
52 permit and shall be shut down until a new permit is issued.

53 A permit for a BSL4 facility shall require compliance with fed-
54 eral and state requirements and standards and other safeguards
55 that the director may require to prevent a release of a toxic biolog-
56 ical agent.

57 A permit for a facility that handles or possess BSL4 shall
58 require the applicant to comply with all sections of this act. Facil-
59 ities must have in effect or to establish without delay, and to
60 enforce, an operating and maintenance manual that complies with
61 the other sections of this act.

62 A permit granted under this section shall require the permittee
63 to report periodically to DPH concerning each experiment under-
64 taken at or proposed for the BSL4 facility. The BSL4 facility
65 shall have its permit revoked if it undertakes any work requiring
66 BSL4 containment that it does not report to DPH. If the BSL4
67 facility is not permitted to disclose the nature of the project by the
68 federal agency that intend on funding it, the facility will not be
69 permitted by the Commonwealth of Massachusetts to accept the
70 funding or conduct the study. Nothing in this paragraph shall be
71 construed as superseding the powers of any district or municip-
72 ality under existing law to enact and enforce restrictions on
73 BSL4 and other biological experimentation consistent with the
74 provisions of this chapter and any regulations issued hereunder.

75 DPH may propose and determine to modify, suspend, or revoke
76 any outstanding permit, in whole or in part, for cause, including,
77 but not limited to, violation of any permit term, obtaining a permit
78 by misrepresentation or failure to disclose fully all relevant facts
79 or any change in or discovery of conditions that calls for reduction
80 or discontinuance of the authorized discharge. The director may
81 also modify a permit at the request of the permittee upon a
82 showing, satisfactory to the director, that the requested modifica-
83 tion is appropriate in view of circumstances for which the per-
84 mittee is not at fault.

1 SECTION 6. No person or persons may transport BSL4 toxic
2 biological agents within the Commonwealth without a license
3 allowing such transport. A general license is hereby issued to any
4 common or contract carrier to receive, possess, transport, and
5 store BSL4 toxic biological agents in the regular course of their
6 carriage for others or storage incident thereto, provided the trans-

7 portation and storage is in accordance with applicable federal and
8 state requirements.

9 The Department of Public Health shall promulgate regulations
10 for the packaging, storage, and transport of toxic biological agents
11 within the Commonwealth. The regulations shall be at least as
12 stringent and protective of the public health, safety, and environ-
13 ment as federal standards. At a minimum, the regulations shall
14 ensure that:—

15 (a) each package meets stringent packaging requirements, is
16 appropriately labeled and stored, and is tracked from sender to
17 receiver;

18 (b) persons who transport BSL4 toxic biological agents receive
19 appropriate training;

20 (c) persons who transport BSL4 toxic biological agents are not
21 known threats to the Commonwealth;

22 (d) procedures are in place to minimize terrorist access to toxic
23 biological agents during transport; and

24 Notification of an incident during transport shall be made to
25 DPH and DEP immediately and in no event later than 24 hours
26 after the incident.

1 SECTION 7. DPH shall establish regulations for approval of
2 emergency response plans, which will include:—

3 (a) The facility shall work with Local, State, and Federal offi-
4 cials to develop an emergency response plan to security threats.

5 The plan shall incorporate security measures and personal with
6 local state officials.

7 The plan(s) shall incorporate all potential threats.

8 The facility shall work with Local, State, and Federal officials
9 to develop an emergency response plan to respond to contamina-
10 tion threats.

11 No BSL4 facility without an emergency response plan shall
12 receive a permit.

13 All emergency response plans shall be included in each facili-
14 ty's operation and maintenance manual.

1 SECTION 8. Contingent Liability Account and Institutional
2 Control Account Established.

3 Each BSL4 facility shall establish a contingent liability account
4 and an institutional control account. The Institutional Biosafety
5 Committee shall determine annually the amount that shall be
6 deposited within each account; provided, however, that after such
7 deposits, no amounts so deposited may be transferred between
8 such accounts.

9 The contingent liability account shall be used to pay compensa-
10 tion for injuries to persons, land or property resulting from the
11 management of materials categorized as BSL4.

12 The institutional control account shall be used to pay institu-
13 tional control. The account shall be used by the board to purchase
14 insurance coverage or otherwise to ensure the availability of funds
15 to meet liability claims during the institutional control period;
16 provided, however, that no portion of the monies held in the insti-
17 tutional control account may be used to satisfy judgments or set-
18 tlements for any other purpose other than institutional control of a
19 facility.

20 The Department of Public Health shall conduct an annual
21 review and analysis of the adequacy of available funds and insur-
22 ance protection against personal injury and property damage,
23 including third-party liability insurance attributable to any BSL4
24 facility.

1 SECTION 9. A person who violates this act is subject to judi-
2 cially imposed criminal and civil penalties as well as civil admin-
3 istrative penalties imposed by DEP or DPH. Each day that a
4 violation occurs or continues constitutes a separate violation.

5 A violation may be punished under the statute by the imposi-
6 tion of a penalty that does not exceed \$25,000 for each day of vio-
7 lation.

8 A violation may be punished by the administrative imposition
9 of a penalty of no less than \$100 and not more than \$25,000 for
10 each day of violation.

11 A violation may be punished under the statute by a fine of not
12 more than \$25,000, or by imprisonment for not more than two
13 years in a house of correction. Punishment imposed under the
14 statute is in addition to any other penalty prescribed by law.

15 A facility's BSL4 permit may be permanently or temporarily
16 revoked for any violation of this Act.

1 SECTION 10. Each facility with a BSL4 laboratory shall have
2 an Institutional Biosafety Committee (IBC). At least two mem-
3 bers of the IBC shall be from the municipality in which the
4 facility is located and shall be outside members who are indepen-
5 dent of the facility, as approved by the Department of Public
6 Health.

7 The IBC shall comply with federal requirements for an IBC.

8 The Department of Public Health shall establish further regula-
9 tions for the composition, operation, and requirements of the IBC.
10 Those regulations shall require that the IBC keep public minutes
11 of its meetings and file an annual public report of its operations
12 and decisions with the Department of Public Health.

1 SECTION 11. Each facility with a BSL4 facility shall have a
2 community oversight board comprised of at least three and no
3 more than five persons appointed by the municipality in which the
4 facility is located, one person, appointed by the Governor, who
5 lives in the community where the BSL4 facility is located, and
6 one person appointed by the facility. The community oversight
7 board shall have the authority to approve in advance all research
8 to be conducted in the BSL4 component, receive reports on
9 ongoing research in the BSL4 component, inspect the laboratory
10 at least annually, and stop BSL4 research in the event of a poten-
11 tial problem subject to the review of the Department of Public
12 Health.

13 The Department of Public Health shall promulgate regulations
14 concerning the membership to and powers of community over-
15 sight boards.

1 SECTION 12. To assure compliance with this Act, and to pro-
2 tect the public health, safety, and the environment, the DPH and
3 DEP are authorized to inspect each facility that has a BSL4 labo-
4 ratory, and review and have a copy of its records, during normal
5 working hours and at other times as required by exigent circum-
6 stances.

1 SECTION 13. Each local municipality within the Common-
2 wealth may enact laws and regulations in addition to those estab-

3 lished by this Act to regulate, limit, or prohibit BSL4 facilities
4 located within their jurisdiction.

1 SECTION 14. Construction and/or operation of any BSL4
2 facility shall not commence until regulations and regulatory
3 authority established herein have taken effect.